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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,891	12/30/2003	Benjamin M. Galkin	GALK-0007	7427

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EXAMINER

YUN, JURIE

ART UNIT	PAPER NUMBER
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2882

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,891

Applicant(s)

GALKIN, BENJAMIN M.

Examiner

Jurie Yun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/12/04, 4/30/04, 5/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The first sentence of the specification should be amended according to the following guideline. Also, the patent number for application 10/302,096, which is USPN 6,850,590, should be noted.

The fact that applicant is entitled to an earlier U.S. effective filing date under 35 U.S.C. 120, 121, or 365(c) or 35 U.S.C. 119(e) is sometimes overlooked. To minimize this possibility, and for the claim to the benefit of the earlier filing date to be proper, the statement that, "**This is a division (continuation, continuation-in-part)** of Application Number -/---, filed ---" should appear as the first sentence of the *specification, or in an application data sheet of applications other than CPAs claiming priority under 35 U.S.C. 120, except in the case of design applications where it should appear as set forth in MPEP § 1504.20.

2. It is noted that both the parent application and the provisional application do not contain support for a partially radiopaque identifier.

MPEP 2133.01 Rejections of Continuation-In-Part (CIP) Applications

When applicant files a continuation-in-part whose claims are not supported by the parent application, the effective filing date is the filing date of the child CIP. Any prior art disclosing the invention or an obvious variant thereof having a critical reference date more than 1 year prior to the filing date of the child will bar the issuance of a patent under 35 U.S.C. 102(b). *Paperless Accounting v. Bay Area Rapid Transit System*, 804 F.2d 659, 665, 231 USPQ 649, 653 (Fed. Cir. 1986).

Specification

3. The abstract of the disclosure is objected to because it consists of more than 150 words. Correction is required. See MPEP § 608.01(b).

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "identifying cover" of claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 14, 18, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Higgins et al. (USPN 6,765,984 B2).

7. With respect to claims 1 and 22, Higgins et al. disclose a comfort device for use with a mammography unit comprising: an x-ray transparent compressible material (Fig. 5, 110) wherein a portion of the identifier comprises indicia (Fig. 13A, 834) which impart information. Higgins et al. also disclose a mammography unit (Fig. 1) comprising a compression paddle (18) and a cassette holder (20). It is noted that the features following “adapted with” do not comprise structural limitations; “a partially radiopaque identifier” is not positively recited.

8. With respect to claims 14 and 18, Higgins et al. disclose (column 2, lines 30+) a method for reducing patient discomfort during a mammogram and for imparting information onto a mammogram, comprising: securing said comfort device, wherein said comfort device comprises an x-ray transparent compressible material (Fig. 5, 110), to a mammography unit comprising patient-contact surfaces (Fig. 1); positioning a patient such that said comfort device is disposed between said patient and said patient-contact

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surfaces; and administering a mammogram. It is noted that "a partially radiopaque identifier" is not positively recited.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins et al. (USPN 6,765,984 B2) in view of Hurwitz (USPN 4,764,948).

11. With respect to claims 1, 2, 5, 6, 14-17, 22, 23, and 25-27, Higgins et al. disclose a mammography unit comprising: a compression paddle (Fig. 1, 18); a cassette holder (20); and a comfort device comprising an x-ray transparent compressible material (Fig. 5, 110). Higgins et al. also disclose (column 2, lines 30+) a method for reducing patient discomfort during a mammogram comprising securing the comfort device (Fig. 5, 110) to a mammography unit comprising patient-contact surfaces, positioning a patient such that the comfort device is disposed between the patient and the patient-contact surfaces, and administering a mammogram. Higgins et al. teach the comfort device can be secured to either a cassette holder or to a compression paddle.

Higgins et al. do not disclose the comfort device is adapted with a partially radiopaque identifier, wherein a portion of the identifier comprises indicia which impart information about said comfort device onto a mammogram. Hurwitz discloses a partially radiopaque identifier (Fig. 4), wherein a portion of the identifier comprises indicia (20)

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which impart pertinent patient and/or imaging information (column 1, lines 14+). The partially radiopaque identifier with indicia (20) is shown in Figure 5 to be applied to a mammography cassette (16) in an area away from a breast image. The identifier is removably attached to a surface via a pressure-sensitive adhesive layer (13). Hurwitz discloses a portion of the identifier is radiopaque, said portion comprising paper or metal or plastic or combinations thereof and said indicia are x-ray transparent (column 6, lines 5+). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the partially radiopaque identifier of Hurwitz to the Higgins et al. comfort device, to provide permanent means for conveying information regarding the comfort device or any other important information. Hurwitz teaches this to be important especially in mammography (column 2, lines 15+). The indicia would be recorded radiographically onto the mammogram.

With respect to claim 3, the information shown in Figure 5 of Hurwitz is the patient's name, but it would have been obvious to one of ordinary skill in the art to provide other information as well, such as physical properties of the comfort device and any other important pertinent information, because any information impacting the results should be made readily available and included for diagnostic purposes.

With respect to claim 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Hurwitz and have the indicia imprinted on the comfort device of Higgins et al., to prevent possible accidental mislabeling, thereby ensuring the information is accurate and correct.

With respect to claims 7, 8, and 13, Higgins et al. disclose the comfort device is configured to define a cavity for containing a cassette holder (see Figs. 9-10C), wherein said material substantially conforms to patient-contact surfaces of said cassette holder and wherein said indicia imparts information onto a first area of said mammogram, and a cassette holder opening (532). Higgins et al. also disclose a second cassette holder opening, both openings adapted to permit a mammography unit cassette to pass therethrough.

With respect to claim 9, Higgins et al. disclose (column 4, lines 48+) the comfort device is configured to define a cavity for containing a compression paddle, wherein said material substantially conforms to patient-contact surfaces of said compression paddle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to also have indicia impart information onto a second area of said mammogram, to provide more information. Providing additional information in a second area would be a way of standardizing the format of information thereby enabling faster means for deciphering the data.

With respect to claims 10 and 24, Higgins et al. and Hurwitz do not disclose the x-ray transparent compressible material comprises a first area comprising a first total linear attenuation value and a second area comprising a second total linear attenuation value, but it would have been obvious to one of ordinary skill in the art at the time the invention was made to include any important information as necessary, including pertinent attenuation values of the material used, because any information impacting the results should be made readily available and included for diagnostic purposes.

With respect to claims 11, 12, and 18-21, Higgins et al. in view of Hurwitz do not disclose a disposable identifying cover comprising x-ray transparent material adapted with a partially radiopaque identifier. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a disposable identifying cover comprising x-ray transparent material adapted with a partially radiopaque identifier, for cost savings. The comfort device could be reused over and over again by just replacing the disposable cover. It would have been obvious to one of ordinary skill in the art to also provide the identifying cover underneath the x-ray transparent compressible material, if there are concerns about the cover being accidentally bumped or moved.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. LeMaitre et al. (USPN 6,333,970 B1), Sheldon (USPN 4,529,635), and Deibel (USPN 5,412,706) disclose the use of radiopaque indicia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Yun whose telephone number is 571 272-2497.

The examiner can normally be reached on Monday-Friday 8:30-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on 571 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jurie Yun
April 26, 2005



Craig E. Church
Primary Examiner